JAN 14 2008 K07 0511

I. *510(k) SUMMARY*

Submitted By:
Richter Rubber Technology SBN BHD
Plot 33, Kuala Ketil Industrial Estate
09300 Kuala Ketil, Kedah
Malaysia

Contact Person:
Eli J. Carter, Consultant
PO Box 12139
Durham, NC 27709
Tel: 919 544 4098; Fax: 919 544 5849
Email: carterej@aol.com

Date Prepared: December 26, 2007

Proprietary Name: None

Common Name: Male Latex Condom: 54 mm (nominal width), 185 mm (nominal length), straight-wall with reservoir tip, silicone lubricated, colorless, flavorless, unscented

Classification Name: Male Latex Condom

Predicate Devices: UNIDUS Male Latex Condom – K023059

Description of Device: This condom is made of a natural rubber latex sheath, which completely covers the erect penis with a closely fitted membrane. This condom is colorless, non flavored, non scented; straight walled with a reservoir tip. The nominal length is 185 mm, nominal width, 54 mm and nominal thickness 0.07mm. It is lubricated with silicone (viscosity 250 cps), and cornstarch is used as a dressing material. This condom conforms to current established national and international voluntary standards including ASTM D3492 and ISO 4074.

Intended Use of the Device:
This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes to help prevent pregnancy and the transmission of sexually transmitted diseases, including HIV.

User Instructions and Precautions are provided to insure proper use and disposal of the product after use. See Package Labeling and Insert – (Attachment 2).

Technological Characteristics:
This condom has the same technological characteristics as the predicate condoms identified above. It is made from natural rubber latex and the design is in conformance with ASTM D3492 and ISO 4074 Male Latex Condom Standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2008

Richter Rubber Technology SBN BHD
% Eli J. Carter, Ph.D.
Consultant
Family Health International
P.O. Box 12139
DURHAM NC 27709

Re: K070511
Trade/Device Name: Richter Male Latex Condom: 54 mm (nominal width), 185 mm (nominal length), straight-wall with reservoir tip, silicone lubricated, colorless, flavorless, unscented
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: December 26, 2007
Received: December 31, 2007

Dear Dr. Carter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

II. INDICATIONS FOR USE STATEMENT

510(k) Number: K070511

Device Name: **Richter Male Latex Condom**
54mm (nominal width), 185 mm (nominal length), straight-wall with reservoir tip, silicone lubricated, colorless, flavorless, unscented

Indications for Use: The Richter Male Latex Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)